K112438(1/2)

APR 11 2012

510(k) Summary

Sponsor	Ascension Orthopedics, Inc. 8700 Cameron Road Austin, TX 78754-3832
Contact Person	Susan Walton susan.walton@integralife.com Phone: (512) 836-5001 x1591 Alternate FAX (512) 836-6933
Date	March 22, 2012
Trade Name	Ascension® TITAN™ Total Shoulder System
Common Name	Hemi- or Total Shoulder
Classification	21 CFR 888.3660 – Shoulder joint metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3690 – Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
Product Code	HSD and KWS
Panel	Orthopedic
Predicate Device	K100448 – Ascension® TITAN™ Total Shoulder System
Device Description	The TITAN Modular Total Shoulder System consists of a line of metaphyseal bodies, humeral stems, humeral heads and all polyethylene glenoid components. The body, stem and humeral head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement. The metaphyseal bodies and humeral stems are shaped to provide proximal fixation and optimal fixation area. Their variable length and proximally-filling shape are designed to accommodate the natural humeral geometry and provide stable fixation, proximal bone loading and proper head placement. The humeral heads are offered with both concentric and eccentric articulating surfaces. The humeral head may articulate against the natural glenoid bone, if it is of sufficient quality, or against the all polyethylene cemented glenoid. The glenoid has two options: keeled or standard pegged (3 pegs). All glenoid options are designed to function with both the concentric and eccentric heads. The humeral components are intended for cemented or uncemented use, while the glenoid component is for use with cement only.
Intended Use	A shoulder joint metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a shoulder joint.
Intended Use	The Ascension TITAN™ Total Shoulder System is indicated for use as a hemi or total shoulder replacement for:

	➢ Severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis. ➢ Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicated that alternativce methods of treatment are unsatisfactory. ➢ Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. – revision of a failed primary component). Shoulder Hemiarthroplasty is also indicated for: ➢ Ununited humeral head fractures. ➢ Avascular necrosis of the humeral head. ➢ Rotator cuff arthropathy. ➢ Deformity and/or limited motion. The humeral component is intended for cemented or un-cemented use. The glenoid component is intended for cemented use only.
Basis of Substantial Equivalence	Ascension Orthopedics believes that this system is substantially equivalent to the legally marketed predicate device based on similarities in design, materials and indications.
Non-clinical Performance Data	Testing to support the material change and additional lengths for the humeral stems has been completed. The testing conforms to ASTM F1378.
Clinical Performance Data	Clinical performance data are not required for the minor changes that are the subject of this Special 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ascension Orthopaedics, Incorporated
% Ms. Susan Walton
Senior Director of Regulatory Affairs
8700 Cameron Road
Austin, Texas 78754

APR 11 2012

Re: K112438
Trade/Device Name: Ascension® TITAN™ Total Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: March 22, 2012
Received: March 23, 2012

Dear Ms. Walton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112438(1/1)

Indications for Use Statement

510(K) Number: _____

Device Name: Ascension® TITAN™ Total Shoulder System

Indications for Use:

The Ascension TITAN Total Shoulder System is indicated for use as a hemi or total shoulder replacement for:

- Severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
- Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicated that alternative methods of treatment are unsatisfactory.
- Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. – revision of a failed primary component).

Shoulder Hemiarthroplasty is also indicated for:

- Ununited humeral head fractures.
- Avascular necrosis of the humeral head.
- Rotator cuff arthropathy.
- Deformity and/or limited motion.

The humeral component is intended for cemented or uncemented use. The glenoid component is intended for cemented use only.

Prescription Use ___X___ OR Over-The-Counter Use _____
(Part 21 CFR 801Subpart B) (Part 21 CFR 801Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112438